

EXHIBIT F



DONALD AND BARBARA
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AT HOFSTRA/NORTHWELL

Written Testimony of Jacqueline Moline, MD, MSc, FACP, FACOEM

**Chairperson, Department of Occupational Medicine, Epidemiology and Prevention at the
Donald and Barbara Zucker School of Medicine at Hofstra University/Northwell Health**

**Director, Northwell Health Queens World Trade Center Health Program
Director, Occupational & Environmental Medicine of Long Island, Northwell Health**

Before the Committee on Oversight & Reform

Subcommittee on Economic and Consumer Policy

United States House of Representatives

“Examining Carcinogens in Talc and Best Methods for Asbestos Detection”

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Jacqueline M. Moline, MD, MSc, FACP, FACOEM

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Jacqueline M. Moline, M.D., M.Sc. is an Occupational Medicine specialist and Professor of Occupational Medicine, Epidemiology and Prevention and Internal Medicine at the Donald & Barbara Zucker School of Medicine at Hofstra/Northwell. She obtained her medical degree from the Pritzker School of Medicine of the University of Chicago. She completed residencies in Internal Medicine at Yale University and Occupational and Environmental Medicine at the Mount Sinai School of Medicine, where she obtained her Masters of Science degree. She is the former Director of the NIOSH funded New York/New Jersey Education and Research Center in Occupational Safety and Health.

After 19 years on the faculty at the Mount Sinai School of Medicine, she joined Northwell Health as the founding Chairperson of the Department of Occupational Medicine, Epidemiology and Prevention. Dr. Moline continues to maintain a clinical practice, focusing on patients with occupational exposures, and has had a particular interest in asbestos exposed individuals. Since 2001, many of Dr. Moline's endeavors have been centered on the medical evaluation and treatment of World Trade Center (WTC) responders. While at Mount Sinai she directed the WTC health program, which she now runs at Northwell Health in Queens, NY. In 2010, Dr. Moline was the recipient of the Kehoe Award of Merit from the American College of Occupational and Environmental Medicine for significant contributions to research in the field of occupational and environmental medicine and she has received numerous awards for her service to WTC responders. Dr. Moline has served as an expert witness in asbestos litigation, including cases involving cosmetic talc.



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Vice President and Chair

Occupational Medicine, Epidemiology and Prevention
Director, Occupational & Environmental Medicine of Long Island
Director, Northwell Health Queens World Trade Center Health Program
Northwell Health

Chair

Occupational Medicine, Epidemiology and Prevention
Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
175 Community Dr., Suite 206
Great Neck, NY 11021
JMoline@northwell.edu

Good afternoon Chairman Krishnamoorthi, Ranking Member Cloud, Members of the Committee.

I am honored to be here this morning. My name is Dr. Jacqueline Moline. I am a board certified physician, specializing in Occupational and Environmental Medicine. I am currently the Chairperson of the Department of Occupational Medicine, Epidemiology and Prevention at the Donald & Barbara Zucker School of Medicine at Hofstra University/Northwell Health. I am the Director of the Northwell Health Queens World Trade Center Health Program and the Director of the New York State funded Occupational and Environmental Medicine of Long Island Clinical Center. My specialty, occupational and environmental medicine, deals with the impact of exposures on the health of individuals. It is part of Preventive Medicine, since we know that individuals without these exposures would likely not be afflicted with the conditions they later develop.

After I completed my Internal Medicine residency at Yale University, I began my training in Occupational and Environmental Medicine at the Icahn School of Medicine at Mount Sinai, where I had the opportunity to study with some of the leading experts in the field of asbestos-related disease. Throughout my numerous roles and job titles, I have dedicated my entire professional life to the studying the prevention and treatment of exposure-related illnesses, including diseases caused by asbestos. Asbestos is one of the most prolific occupational hazards in our country that has caused thousands of deaths in the United States alone. While many countries have banned the use of asbestos, it is currently still permissible to use in the United States. Legislation pending, the Alan Reinstein Ban Asbestos Now Act of 2019 is currently under consideration by Congress. It is time that there is a ban on this deadly substance.

Asbestos fibers are microscopic. To understand how small, approximately 200,000 asbestos fibers could fit on Abraham Lincoln's nose on the penny. Once these fibers are breathed into the body, they can be deposited in the nose, throat, conducting airways, and the alveolar or gas exchanging regions of the lungs. Fibers that land initially on the airway and above are cleared from the body. The fibers that evade the body's initial defense mechanisms can penetrate into the lower lungs and lung tissue, where they can be transported throughout the body. Importantly, they can get to the pleural (chest) cavity and the peritoneal (abdominal) cavity.

The most devastating disease caused by asbestos is mesothelioma. Mesothelioma is a cancer of the lining of the lungs and abdomen, and rarely, the lining of the heart and the testicular sac. The most frequent locations for the tumor is the chest, in the lining of the lung called the pleura. The connection between mesothelioma and asbestos was made based on a case series of 33 individuals who had exposure to the asbestos mines in South Africa¹. Not

¹ Wagner JC, Sleggs CA, Marchand P. Diffuse pleural mesothelioma and asbestos exposure in the North Western Cape Province. Occupational and Environmental Medicine. 1960 Oct 1;17(4):260-71.

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only were the asbestos miners affected, but individuals who lived along the road contaminated by the dust during transportation, and household members of the miners, developed mesothelioma. Mesothelioma is considered a signature disease, meaning that a diagnosis of mesothelioma is almost always indicative of exposure to asbestos. As a result, treating doctors invariably ask patients who were recently diagnosed with mesothelioma how and when they were exposed to asbestos.

For men, evidence of asbestos exposure was often easy to identify. Many of the patients I have been privileged to care for over the years have sought medical surveillance or treatment because they knew that they had worked with asbestos in their careers. From insulators (formerly known as asbestos workers), to steamfitters and sheet metal workers, from former naval servicemen to brake mechanics, their exposures to asbestos were well known. Over 3,000 products were known to contain asbestos. For women, it was sometimes easy to identify, because they lived with someone who worked with asbestos-containing products, and they laundered their family members' asbestos-laden clothes. Newhouse and Thompson described this in 1965². Yet, for many women – and some men – who did not work or live with a person who worked with asbestos, they had no traditional source of asbestos exposure. As a result, their mesotheliomas were considered “idiopathic,” or having no known cause. This discrepancy between the number of mesothelioma cases with identifiable asbestos exposure in women and men lacked a good scientific reason and could not be explained merely by chance.

In my opinion, this conundrum has been solved. The occurrence and commonality of asbestos in cosmetic talcum powder, more commonly used by women, is likely the cause of many women’s mesothelioma, who have no other known asbestos exposure.

To my knowledge, there have been no previous studies of end-users of cosmetic talcum powder. I recently published an article on this topic in the Journal of Occupational and Environmental Medicine³. As Wagner did in 1960¹, my colleagues and I reported on 33 individuals with no other identifiable source of exposure apart from cosmetic talc. In this case series, we reported in depth on six individuals for whom tissue digestion analysis was performed. This testing, in addition to their history of consistent use of cosmetic talc, identified asbestos and talc fibers in their tissue. Years ago, other scientists evaluated lung burdens of women with mesothelioma. They found the types of asbestos commonly found in talcum powder in their lungs. They stated that these asbestos fibers might be related to the use of contaminated cosmetic talc^{4,5}. In these papers, there was no information regarding whether these women had been asked about their use of cosmetic talc. This is characteristic of virtually all studies of mesothelioma. Because there was a general unawareness in the medical literature that asbestos was present in talcum powder, clinicians did not ask about the use of cosmetic talc, nor did they think of it as a potential source of asbestos exposure.

It can be helpful to hear about an individual to better understand how cosmetic talc usage might impact one’s health. Ms. D. was a 66 year old woman who developed shortness of breath, chest wall pain and fatigue. She was

² Newhouse ML, Thompson H. Mesothelioma of pleura and peritoneum following exposure to asbestos in the London area. Occupational and Environmental Medicine. 1965 Oct 1;22(4):261-9.

³ Moline J, Bevilacqua K, Alexandri M, Gordon RE. Mesothelioma Associated with the Use of Cosmetic Talc. J Occup Environ Med. 2019 Oct 10. doi: 10.1097/JOM.0000000000001723. [Epub ahead of print] PubMed PMID: 31609780.

⁴ Churg, A. Warnock ML. Asbestos and other ferruginous bodies. Am J Pathol. 1981; 102:447-56.

⁵ Roggli, Victor, et al. Tremolite and Mesothelioma, Ann Occup Hyg. 2002;46(5):447-53.

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started on diuretics, anti-anxiety and anti-depressant medication by her personal physician. An evaluation of her heart showed no abnormalities. Her shortness of breath continued, and two months later, a chest x-ray showed fluid surrounding the lung. She had a procedure to remove the fluid, known as a thoracentesis, and 1,600 milliliters of fluid was removed - more than three of the water bottles on this table in front of me. Malignant cells were noted in the fluid. She continued to have shortness of breath, and had lost 25 pounds in three months. Four months after she developed symptoms, she underwent a surgical procedure called a thoracoscopy, to evaluate the lining of the lung and take tissue samples for diagnosis. She had pleural nodules throughout her chest. The pathology showed malignant mesothelioma. Ms. D. also had a pleural plaque, a hallmark finding of prior asbestos exposure usually seen in individuals who worked with asbestos containing products. Ms. D. underwent chemotherapy, as well as extensive surgery to remove the tumor and the lining of her lung. She later received more chemotherapy but it was unsuccessful, and she passed away two years after her initial diagnosis.

Ms. D. had no significant medical history and was a non-smoker. She worked in the textile industry, working with polyester and cotton yarns. She also worked for a tobacco company as a packer. She had no known exposure to asbestos in these jobs, or from home construction activities. She did, however, have exposure to cosmetic talc in two settings: she worked as a hairdresser, and she used cosmetic talc on her body. As a hairdresser, she applied talcum powder to the necks of her customers after she cut their hair. She poured the powder onto her hand and used a brush, or sprinkled it directly onto the clients' necks from the bottle. She was a hairdresser for 25 years. Ms. D. used cosmetic talcum powder on her body for 30 years. Her mother applied the talcum powder onto her after her bath when she was young, and she continued this practice when she was older. She used a powder puff to apply the powder, and noted that there would be a "puff of smoke and it went everywhere." She had to clean up the excess powder, providing another opportunity for exposure to the talc and asbestos. It is important to realize that the cosmetic talc – and asbestos – can linger after the initial application time, and in some cases, affect the health not only of the principal user, but also family members who might clean up or be present during their family member's use of the talcum powder.

In our study, the average age of the patients was 57 years, with an age range from 27 – 88 years at the time of diagnosis. Nineteen cases arose in the pleural cavity, and 14 cases arose in the peritoneal cavity. The average number of years that individuals used cosmetic talc averaged 32.7 years, with a range of use from 10-80 years. The cosmetic talcum powder use was not confined to one brand; there were twenty-two different brands of talcum powder used by participants. Like Ms. D., patients often used more than one type of cosmetic talcum powder during their lives. Many of the cosmetic talcum powders were sourced from the same mines or same areas, such as Italy and Vermont. More recently, talc has been sourced from China. Samples of ore have been found to contain asbestos in numerous samples, and the finished products have as well. These issues have been documented in the medical literature for over 50 years.

Fortunately, mesothelioma is a very rare tumor, even among individuals with frequent exposure to asbestos. Around 3,000 new cases of mesothelioma are diagnosed each year in the United States. Unfortunately, mesothelioma is not considered curable. Five year survival rates for pleural mesothelioma are less than 5%.⁶ Chemotherapy has increased the survival rate from 7 months with no treatment to an average of 9-13 months with chemotherapy. Aggressive surgery in candidates who are eligible for surgery (meaning their mesothelioma is confined to the chest, is a more favorable cell type, and patients are able to withstand a large operation) can prolong life. When combined with radiation and chemotherapy, it can lead to an increased survival rate, up to 10-

⁶ Skammeritz E, Omland LH, Johansen JP, Omland Ø. Asbestos exposure and survival in malignant mesothelioma: A description of 122 consecutive cases at an occupational clinic. Int J Occup Environ Med (The IJOEM). 2011 Oct;2(4):224-36.

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35 months⁷. Unfortunately, only around 20% of pleural mesothelioma patients qualify for this surgery. Survival rates for peritoneal mesothelioma, or mesothelioma in the lining of the abdomen, is better. For peritoneal mesothelioma, the overall 5 year survival rate is 39%⁸. The average survival rate for patients undergoing extensive surgery and chemotherapy in their abdomen is 67 months⁹.

In addition to mesothelioma, more and more evidence is coming to light to support the proposition that cosmetic talcum powder is causing some women's ovarian cancer as well. The scientific evidence is clear that asbestos causes ovarian cancer¹⁰. Recent studies that have looked at perineal talc exposure and ovarian cancer risk have found elevated cancer risk, particularly for the most common type of ovarian cancer: serous carcinoma of the ovary^{11, 12}. The authors of these papers do not differentiate between the risk of talcum powder itself and asbestos as a contaminant of the talcum powder.

The definition of asbestos is subject to a lot of discussion and opinions. As a physician treating patients with asbestos-related diseases, what matters to me is not what something is called, but whether it is capable of causing disease. Is the particle small enough to penetrate deep into the lung? The body does not care how the fiber or particle grew in the earth. As the Chilean researcher Oyarzun stated, the issue from a public health standpoint is whether the mineral is capable of causing disease¹³. The rest is a semantic exercise. In 2019 The Finnish Institute of Occupational Medicine provided a definition of asbestos that states that “asbestos fibers with a thickness of 3 micrometers or less and a length of 5 micrometers or more cause a risk of cancer and pulmonary diseases when inhaled, regardless of whether they have been formed as a result of a geological process metamorphism or in an industrial process, such as in mining operations”¹⁴. I'm sure there will be further discussion from the other learned members of the panels today on this issue. However, as a doctor, what matters to me is not the nomenclature. Whether you call it a cleavage fragment or asbestos, any particle of chrysotile, amosite, crocidolite, anthophyllite, tremolite, and actinolite that is small enough to be inhaled, and has at least a 3:1 or 5:1 length to width ratio, is capable of causing disease, including deadly mesothelioma. Using terminology to somehow differentiate whether a particle is asbestos (like asbestos), or a “cleavage fragment” obfuscates the issue. Is the particle one of the six asbestos minerals, is it in fibrous form, and can it become airborne, so that it can be breathed into the lung? From a clinical perspective, it is really quite simple.

⁷ Sugarbaker DJ, Wolf AS. Surgery for malignant pleural mesothelioma. Expert review of respiratory medicine. 2010 Jun 1;4(3):363-72.

⁸ <https://www.asbestos.com/mesothelioma/statistics/>

⁹ Sugarbaker PH, Welch LS, Mohamed F, Glehen O. A review of peritoneal mesothelioma at the Washington Cancer Institute. Surgical oncology clinics of North America. 2003 Jul;12(3):605-21.

¹⁰ Camargo MC, Stayner LT, Straif K, Reina M, Al-Alem U, Demers PA, Landrigan PJ. Occupational exposure to asbestos and ovarian cancer: A meta-analysis. Environmental health perspectives. 2011 Jun 3;119(9):1211-7.

¹¹ Kadry MT, Farhat N, Karyakina NA, Shilnikova N, Ramoju S, Gravel CA, Krishnan K, Mattison D, Wen SW, Krewski D. Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer. Reproductive toxicology (Elmsford, NY). 2019 Dec. 90:88-101.

¹² Berge W, Mundt K, Luu H, Boffetta P. Genital use of talc and risk of ovarian cancer: a meta-analysis. European Journal of Cancer Prevention. 2018 May 1;27(3):248-57.

¹³ Oyarzun R, Lillo J, Oyarzun J, Maturana H, Canut C, Andreani S. Restrictive definition of asbestos and the assessment of potential health hazards: insights from Northern Chile. International Geology Review. 2010 Jun 21;52(9):955-63.

¹⁴ Kähkönen, H., Lallukka, H., Linnainmaa, M., et al. Asbestos Risk Management Guidelines for Mines, Finnish Institute of Occupational Health. Helsinki 2019.

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Millions of individuals have been exposed to asbestos from contaminated talcum powder. There are safer alternatives on the market that do not contain talcum powder or asbestos. My specialty of occupational and environmental medicine strives to identify, treat and prevent future illnesses related to exposures and hazards. If there is any possibility of the presence of asbestos, why should we take the chance?

I would be happy to take your questions.